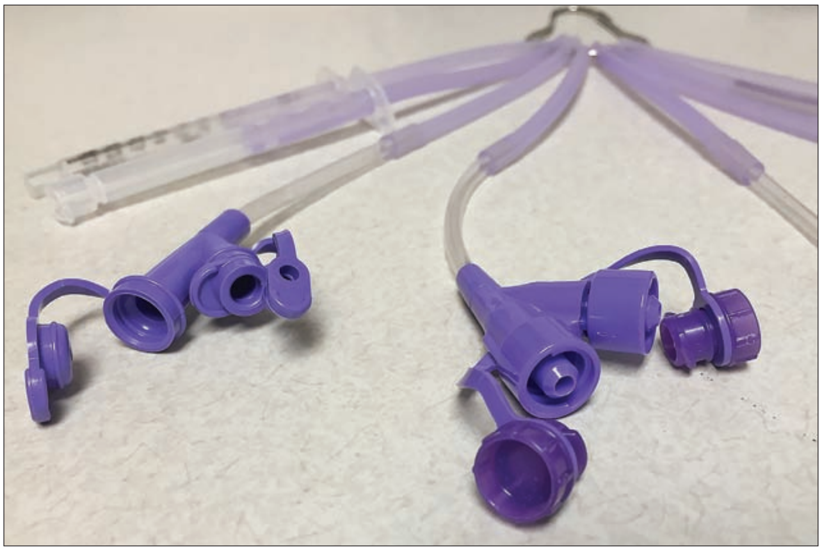
Enteral tubing connection changes: A failure modes and effects analysis

By Heidi L. McNeely, MSN, RN, PCNS-BC, and Sasha Jacobs-Lowry, BSN, RN, CPN



Medical tubing misconnections have been reported for years. Although the problem still exists, the events are likely underreported.[1] Misconnections have resulted in death or major harm to patients and have the potential for causing secondary trauma for the nurses who make the error.[2-5] The ability for misconnections to occur continues to point to the need for a redesign of current connectors.[6] An alert from The Joint Commission was issued to notify healthcare facilities about the risk of small-bore tubing (less than 8.5 mm inner diameter) misconnections and encourage facilities to put plans in place to limit the risk of misconnections and transition to new standards.[7] A group of clinicians, manufacturers, and regulators collaborated with the International Organization for Standardization (ISO) and the Association for the Advancement of Medical Instrumentation to develop ISO 80369 standards for small-bore tubing connections.[8]

The standard 80369-3 is specific to enteral tubing designs.[8]

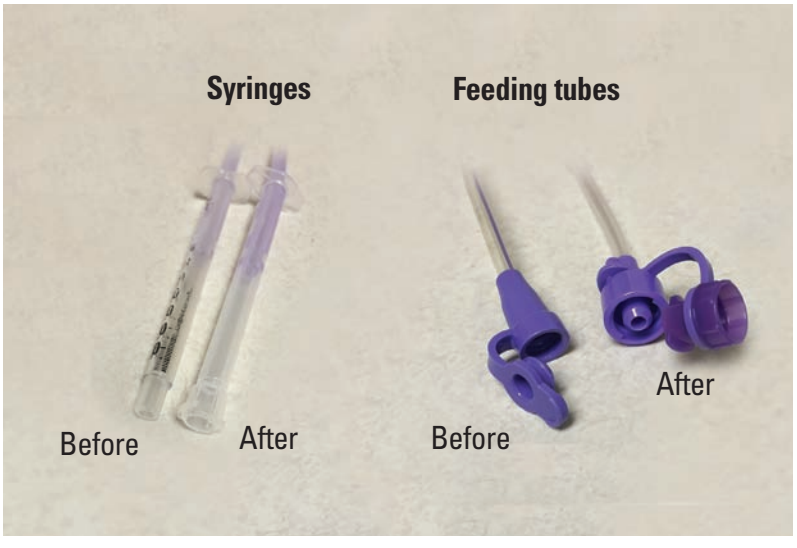
The proposal was to change feeding tubes with female end connectors to male end connectors and current medication syringes used for enteral administration from male tip connections to female tip connections. (See *Figure 1*.) The reverse orientation of connections is expected to aid in reducing the possibility of misconnections of enteral tubing with other small-bore tubing, such as I.V., urologic, respiratory gas, air inflation cuff, and neuraxial tubing. These new connections are also a threaded design instead of slip tip. The ISO standard for these changes didn't specify an orientation requirement (male versus female), but it does set the standards for shape, size, physical properties, functional performance, and material characteristics.[8]

Initially in 2015, there were concerns about accurate medication dosing using the new syringes.[9,10] These concerns stemmed from dead space at the end of the syringe that could cause problems with medication excess or loss of medication during administration. To appropriately deliver an accurate dose and avoid issues with the dead space in syringes, there are additional supplies used for medication preparation, such as medication straws and bottle cap adapters. The addition of adapters poses further risks, such as confusion, inconsistent use in practice, increased cost, drug wastage from the amount left in adapters or spillage, and choking hazards for pediatric patients. Some of these concerns were recently addressed with the low-dose tip syringe.[11] However, limited data are available showing the performance of these syringes in practice. A recently published article demonstrated that there are still risks of dosing inaccuracy and workflow complexity.[12]

In pediatric settings, the healthcare team often needs to use adaptive devices or products for unintended purposes to meet the medical needs of their pediatric patients.[13,14] Products may not be approved for pediatric use or the specific products needed may not be available, which leads to off-label use of available products. Due to these gaps and not all needs being addressed with compatible supplies, many hospitals have decided to delay their go-live dates or put them on hold until further developments provide a safer transition process. Additionally, organizations have attempted to determine the cost implications of this change. Although much is still unknown, it's likely that costs will be increased with new tubing, syringes, and adapters due to the need for supplies (such as adapters and cleaning brushes) not previously needed with legacy products.

Some experts feel the only true way to prevent misconnections is to ensure that the connections for different types of small-bore tubing are physically incompatible.[13] Although much work has been done, the actual conversion to these new connectors has lagged due to many issues: facilities are unaware of the recommended changes or have no specific timeline to change; there's no requirement for organizations to make the change (except in California where legislation exists[15]); limitations in supplies from manufacturers; variations in available options with additional adapters to facilitate the transition; not all syringe and tube manufacturers are producing the same design, causing incompatible options for enteral tubing;[16] not all enteral products are being manufactured with the new connections; and uncertainty with the use of new tubing for blenderized tube feedings.[17]

Figure 1: Current legacy products vs. new products



In the meantime, hospitals have been encouraged to complete risk assessments of their current practices and determine what steps are needed to decrease risks and help facilitate a smoother transition.[13] Although not required for organizations outside of California, the recommendations are to not delay the conversion and avoid disruption of enteral therapy for patients through a well-planned and methodical transition, which ideally should have started from 2017 and into 2018.[18] Clearly, concerns about the uncertainties and workarounds (use of adapters for an extended period of time) with the proposed solution and barriers to transition still exist as we're reaching the end of 2019 and still seeing slow movement toward the change.

At a large, private, nonprofit pediatric academic hospital, the implementation of a global standard for enteral tubing connections was assessed using a failure modes and effects analysis (FMEA). A lack of mitigation strategies to address potential failures involved with enteral tubing changes was identified, which would impact multiple stakeholders, departments, and clinical workflows. In this article, we summarize the hospital's development of an interdisciplinary team to discuss potential risks related to the implementation of enteral tubing changes. The intent is to share highlights from the FMEA and a list of potential risks that were identified. Although performed at a pediatric facility, this work isn't specific to pediatric healthcare and may help nurse managers at other institutions facilitate discussions to ensure that they understand the implications for nursing practice and address potential risks to patient safety earlier in their transition planning.

Methods

No formal approvals, such as from the Institutional Review Board, were obtained; both the hospital's chief quality officer and CNO provided executive-level sponsorship. In Fall 2014, an internal team was convened to discuss and anticipate potential failures of the enteral tubing connection changes. The clinical nurse specialist, medication safety nurse, pharmacist, and purchasing representative served as the team leaders. Additional interdisciplinary representatives from nursing, pharmacy, accreditation, patient and medication safety, professional development, surgery, gastroenterology, nutrition, and case management were invited to participate. Representatives were either asked to participate because of their knowledge of feeding tubes or volunteered to represent the departments most affected by the proposed changes. The purchasing representative generated a report to determine all areas of the hospital that used feeding tubes. This report allowed the team to recruit from areas not yet represented, as well as identify areas potentially using feeding tubes for off-label use.

Up to this point, the hospital hadn't experienced any misconnections. However, given the international incidence and attention to misconnection prevention, it decided to proactively assess the risks and determine next steps regarding the new enteral tubing connections. Clinical nurses and pharmacists were involved in testing a prototype of a new enteral small-volume syringe but were purposely left out of the original stakeholder team because of time commitments needed and an unknown transition timeline. Due to the complexity of the change, clinical stakeholders with awareness of current practice and workflows and experience with FMEA were engaged. Clinical nurse team members will be more actively engaged when product selection occurs and the transition timeline is determined.

The team felt that an objective and thorough process was necessary to consider the potential failures and harm that may come from these changes. The medication safety nurse decided to facilitate the process in 2015 using Six Sigma methodology. The team began with the largest workflow and wrote out process maps for nursing and pharmacy. (See *Figure 2*.) The bulk of the workflow failures were captured through these process flows. Then, the team drilled down within each step in the process flow to initiate the FMEA and identify the biggest issues around safety and the transition strategy. Once failures were identified, the team brainstormed potential mitigation strategies and discussed the potential harm that would occur if these failures happened.

The FMEA uses a rating system and calculation to help develop a risk score for each potential failure in the process. Each failure is scored based on severity, likelihood of occurrence, and likelihood of detection. The FMEA version used by the team was an internally created adaptation based on other published tools, such as the one found in "Failure Modes

Table 1: FMEA example template

FMEA															
Process step number	Item/ process step	Potential failure mode (what)	Potential effect(s) of failure (consequences)	Severity (SEV)	Potential cause(s)/ mechanism(s) of failure	Occurrence (OCC)	Current control	Detection (DET)	Risk priority number (RPN)	Recommended action(s)	Responsibility and completion date	Action results				
												Actions taken (Recalculate RPN post implementation)	S E V	O C C	D E T	R P N

Figure 2: Process map for medication workflows using different oral and enteral supplies

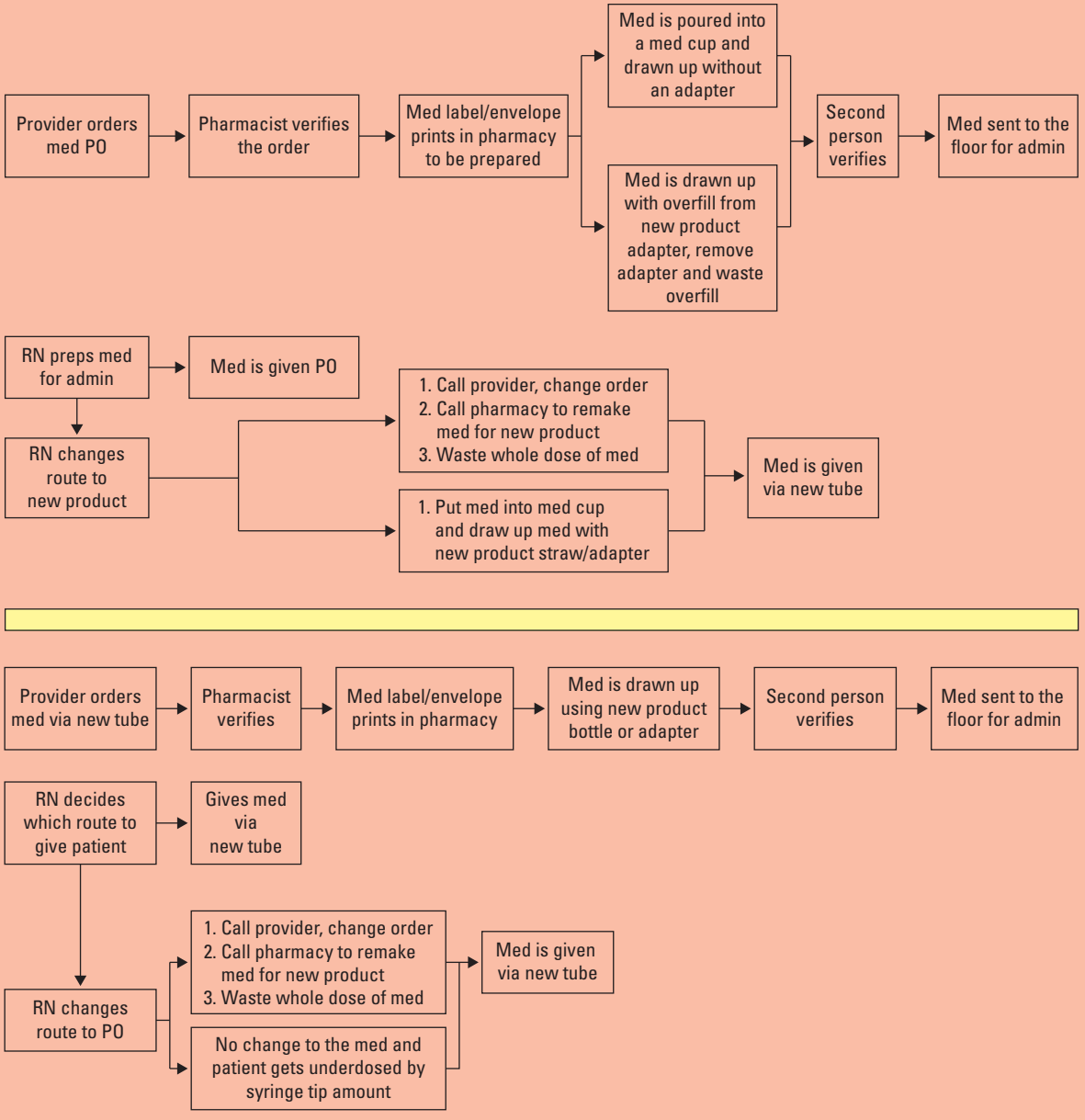


Table 2: FMEA sample ratings criteria

Rating	Severity of effect (How bad is it?)	Rating	Likelihood of occurrence (How often does it happen?)	Rating	Likelihood of occurrence (How often will controls detect failure?)
How severe is the effect to the patient?	What's the effect of each failure mode on the patient/process?	How often does the cause or failure mode occur?	How can the failure occur?	How well can you detect cause or failure?	What are the existing controls that either prevent the failure mode from occurring or detect the failure should it occur?
10 Extreme	• ***Multiple deaths***	**10 Almost certain**	• Failure highly likely to occur, is almost inevitable • Failure likely to occur in greater than 10% of opportunities	**10 Very remote**	• Can't detect failure
7 High	• ***Major permanent loss of function:*** Lessening of bodily functioning, disfigurement, surgical intervention required, increased length of stay or level of care	**7 High**	• Relatively high failure rate • Failure likely to occur in 1% of opportunities	**7 Low**	• Very low/remote chance of detecting or preventing the failure before reaching patient
4 Moderate	• ***Temporary harm:*** Length of stay or level of care required, but no lasting or permanent harm done to patient	**4 Low**	• Occasional failures • Failure may occur in 0.1% of opportunities	**4 High**	• Good chance of detecting or preventing the potential failure before reaching patient
1 Little to none	• ***No harm:*** No injury, increased length of stay, or increased level of care • Failure may occur but doesn't reach or harm patient	**1 Remote**	• Failure is unlikely • Failure may occur in 0.01% of opportunities	**1 Very high**	• Almost certain detection

and Effect Analysis: Templates and Tools to Improve Patient Safety."[19] It simplifies the scoring from a 1-to-10 scale to either 1, 4, 7, or 10 to help prioritize and rank failures based on levels of risk. (See *Table 1* and *Table 2*.)

The team completed the FMEA using the following process. The team convened for an initial in-person meeting to discuss process steps involved in enteral tube medication and feeding delivery. They engaged in a collaborative approach by asking each participant to use small sticky notes to write down what potential failures they were worried about and place them on the wall next to the steps in the process where these failures may occur. The project leads compiled lists and entered them into the FMEA template. The whole team then scored and ranked the potential failures within the template. They reviewed the risk scores for each failure and determined that those with the highest scores represented the issues that were most clinically significant.

The team completed two separate FMEAs. One version covered the scenario if the hospital made the decision to only stock new syringes and tubes. The second was done for stocking and using both oral slip-tip syringes and the new syringes. Based on the risk score, the team narrowed down the steps involved that pose the greatest risk to patients. Next, the group discussed if a new system

design could prevent these risks from happening. If the risks were too great without effective mitigation strategies, then a decision to delay or avoid the transition to new devices may occur.

Table 3: Highest identified risks from FMEA

	Process step or function	Potential failure mode	Potential effect(s) of failure
	Include step from process map in all rows for sorting	Failure or symptom evidenced in the output	Impact on patient requirements
2.1	Pharmacy prepares med	Stocking of supplies	Patient gets overdosed or underdosed
		Prepares wrong volume	Patient gets overdosed
		Prepares wrong volume	Patient gets underdosed
3.1	RN prepares med in med room	Prepares wrong volume	Patient gets overdosed
		RN changes the route from new product to PO	Patient gets underdosed
		RN changes the route from what was ordered	Patient becomes nontherapeutic on time-critical meds

Results

The compilation of results from the two FMEAs identified 73 potential failures. Early in the process, the team determined that there was less potential for failures if the hospital planned to transition with only new products instead of keeping both oral syringes and the new enteral syringes in stock. (See *Table 3*.) General risks related to workflow changes required by the new products were grouped within five main categories: pharmacy preparation of medication, nursing preparation and administration, healthcare provider ordering, supply issues, and home care/discharge issues outside of the hospital. (See *Table 4*.) There will likely be risks and mitigation strategies employed that are unique to each organization and their supply chain.

The primary mitigation strategy identified for these risks was staff, healthcare provider, patient, and family education. Additional mitigation strategies included the recommendation for only stocking new syringes; copackaging the required adapters with syringes; identifying off-label uses before implementation; limiting or eliminating the use of adapters as much as possible; planning a clear, comprehensive transition strategy; coordinating care with discharge planning; and delaying the transition.

Discussion

Currently, there's no difference in the pharmacy's preparation of medication for oral and enteral tube delivery because the syringes and volume accuracy are the same for either route. If the hospital chose to stock both oral syringes and the new syringes, there could be potential risk for medication volume errors (underdose or overdose) during pharmacy preparation if the wrong syringe is used based on the actual delivery route. Ultimately, the team determined that the risks would be too great to stock both oral syringes and the new syringes, making the decision to only have the new syringes available once transitioned. The FMEA helped make this decision, but other factors were considered, including limited storage space to stock both product versions, requiring the healthcare provider to specify only one route when placing the order while taking this clinical decision away from nursing at the bedside, and ensuring all staff members understand the differences between how to accurately draw up correct medication doses if keeping both syringes.

After completion of the first two FMEAs, the team worked up a third FMEA to plan for the potential of a patient arriving to the hospital with a new device before the hospital made the transition. The team agreed that based on the results of all three FMEAs, it would be better to make accom-

SEV	Potential contributing factors to failure	OCC	Current process controls prevention	Current process controls detection	DET	RPN
How severe is the effect on the patient?	Causes to input failure; add row for each cause within step/input	How often does cause or failure mode occur?	Existing controls that prevent the cause or the failure mode	Existing controls that detect the cause or failure mode before defects escape	How well can you detect cause or failure mode?	Risk priority number
7	Not enough room to stock both syringes and supplies and so use whatever syringe is closest	10			10	700
7	Draw up med for PO with new product supply	7			10	490
7	Draw up med for new product with PO supply	7			10	490
7	Don't use adapter to draw up med for new product admin	7			10	490
7	RN can't get med out of the tip of the syringe	7			10	490
10	RN manipulates med in med room for change in route	4			10	400

modations for this patient population rather than moving forward and transitioning before all the other risks were addressed. The hospital decided to stock one adapter for use if a patient arrived with a new device before the full transition. This adapter allows for all legacy products to be connected to the end of the new tubing. The adapter would remain in place during the entire admission or until requiring cleaning or changing.

In the meantime, it's important to educate and communicate key messages so healthcare providers are aware of and can begin to prepare for the changes. At the statewide level, the team is actively leading a task force among other hospitals, home care companies, pharmacies, and suppliers to share information and gain a better understanding of the current status of the issue. At the national level, the hospital's nurse leaders have urged manufacturers to collaborate for one solution to meet the needs of patients and limit the use of adapters as much as possible.

Additional barriers continue to create complexity, and some organizations have converted whereas others continue to wait. Although there are no specific criteria for determining when to go live, the following issues may be worth considering and addressing before implementation: syringes should be available over the counter without a prescription, there should be limited need for and use of adapters, and the ability to transition all products at the same time should exist due to lack of space to accommodate legacy products and new supplies. In addition, we need a better understanding of the effectiveness of cleaning tubes to prevent bacterial growth, clogging, or compromised connections; different options of tubes/syringes available that meet the ISO standard; workflow risks with the new syringes collecting medication/liquid in the tip of the syringe (such as hazardous drugs, dosing accuracy, and cleanliness of the medication preparation process); and plans for future

Table 4: General risks categorized

Category	Risks
Pharmacy preparation of medication	Dose preparation errors due to improper use of supplies or unawareness; prefilled medication syringes not available from vendors; incorrect technique with new syringe leading to inaccurate dose
Nursing preparation and administration	Hazardous drug exposure with need to manipulate medications in new syringes; dosing accuracy if using a larger-than-necessary syringe for small-volume doses or not appropriately using low-dose syringes; inaccurate technique with new syringe leading to inaccurate dose; concerns about crushed or viscous medications or blenderized feeds affecting patency of the syringe/tube; concerns around safe medication delivery to neonatal patients (larger off-label uses of enteral tubes and the ability to identify all off-label uses before transition)
Provider-specific	Remembering that there's a prescription requirement for low-dose tip syringes; primary care providers and home care agencies may receive an increased number of calls related to issues with new devices; may not be able to troubleshoot issues
Supplies	Gastric tube balloon inflation connection for skin-level enteral devices uses a slip-tip syringe, two different syringes required for these devices; backorder potential on new supplies; will require use of and education on adapters; not all products are available for complete transition; would need to stock both new and legacy products for a long period of time; multiple different adapters available, each with different risks; limitations in storage space during transition; no coordinated transition time frame across the country or regionally
Home care/ concerns after discharge	Patient's inability to obtain necessary supplies; not all retail pharmacies aware of transition; may not stock new syringes; low-dose syringes not used or larger-than-necessary syringe used, resulting in dose inaccuracy; home care supply company not being able to meet the needs of a patient's readmission because of an inability to get necessary supplies outside of the hospital

developments and/or regulation around the products and the overall transition.

Toward a safe transition

At the conclusion of the FMEA process, the hospital identified weak or no clear mitigation strategies for most of the risks associated with enteral tubing changes. Many of the identified failures relied on education as a mitigation strategy; however, education alone isn't an effective intervention for reliable and sustained change. Although the stakeholder team discussed the impact of education for nurses, healthcare providers, pharmacists, and community partners, this doesn't suffice for a safe transition. At this time, the hospital will continue to use legacy products given the potential risks. The hospital is actively engaged with other organizations and manufacturer groups to learn from the experiences of facilities that have already transitioned. Ongoing discussions with larger collaborative groups continue for information sharing and to help address risk mitigation strategies. Results of the FMEA have been shared with the hospital's leadership and patient safety committee for assistance with planning a safe and successful transition in the future. NM

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